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UPDATE ANNOUNCEMENT

Dear Colleagues:

We?re writing to update you on Contract 1406-04-08-RP-20201 for a "National Cancer Institute (NCI) Data Capture and Management System for Cancer Clinical Research." This contract was awarded to Medidata Solutions Inc., effective August 10, 2009, pursuant to a full and open competition under the Federal Acquisition Regulation (FAR) Part 12 ("Acquisition of Commercial Items") and FAR Part 15 ("Contracting by Negotiation") by the Acquisition Services Directorate/National Business Center/US Department of the Interior on behalf of the National Cancer Institute.

The Government Accountability Office (GAO) has concluded its review of the protest Velos, Inc. filed with respect to the subject procurement and has sustained the protest. To date, GAO?s decision is not available for public release and therefore, we are unable to discuss it in detail. In the meantime, NCI plans to continue with acceptance testing activities pursuant to the contract terms while we evaluate the decision and ascertain the appropriate response to GAO?s corrective action recommendation

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Medidata Rave Demo Videos Links

Currently the NCI offers access to three Medidata Rave Demos:

- **Overview Demo**

- **Study Build and Reporting**

- **Integrations Discussion**

If you would like to access any of the three demos, please send an email to ncicabigcdms@mail.nih.gov to receive the links to the demos. Please be sure to include the title of which demo you would like to view.

Special Announcement

Request for letters of intent to adopt NCI-procured Clinical Data Management System - deadline Tuesday 12/15/2009

Please see the attached word document for information and instructions regarding the NCI's request for non-binding letters of intent from organizations that may be interested in adopting the CDMS software within approximately the next two years, irrespective of planned deployment option.

Image:Request for LOI (CDMS).doc

Also please find attached the Rave System Requirements specification sheet for your reference.

Image:Rave System Requirements v10 23-7-091.pdf

CDMS Award Announcement

Contract 1406-04-08-RP-20201 for a "National Cancer Institute (NCI) Data Capture and Management System for Cancer Clinical Research" has been awarded to Medidata Solutions Inc. (Medidata), 79 Fifth Avenue, New York, NY 10003. This acquisition was conducted as a full and open competition under the Federal Acquisition Regulation (FAR) Part 12 ("Acquisition of Commercial Items") and FAR Part 15 ("Contracting by Negotiation") by the Acquisition Services Directorate / National Business Center / US Department of the Interior on behalf of the National Cancer Institute. This award was made following corrective action requested by the US Government Accountability Office (GAO), in accordance with procedures established pursuant to the Competition in Contracting Act of 1984 (CICA), 41 U.S.C. 253.

NCI has purchased licensing rights to use and distribute a Clinical Data Management System (CDMS) software package throughout the NCI Cancer Research Enterprise, defined as government and NCI-supported not-for-profit research institutions that conduct clinical and related human subjects research in the field of cancer as defined presently or in the future. These include, but are not limited to, NCI-designated Cancer Centers; NCI Clinical Trials Cooperative Groups; research organizations that the Institute funds as Specialized Programs for Research Excellence (SPOREs); NCI Community Clinical Oncology Programs (CCOPs) and Minority-Based Community Clinical Oncology Programs (MBCCOPs); and components of the National Community Cancer Centers Program (NCCCP). Under the terms of this license, institutions that choose to adopt the CDMS will be eligible to receive related support services and software maintenance. In addition the NCI has procured installation services at fifty-five (55) institutions (although there is no limit on the number of institutions that may install or use the software).

Over the next few weeks additional information will be made available describing the process by which institutions may request and receive the software from the NCI. In the meantime, you can see a list of <u>frequently asked questions.</u>

CDMS Procurement Guidelines

- NCI is purchasing licensing rights for a commercial clinical data management system (CDMS) software product

   ♦ aka Remote Data Entry (RDE) or Electronic Data Capture (EDC)
- Will be made available free of charge to all organizations in the NCI Clinical Research Enterprise

   ♦ (i.e., all NCI-supported organizations conducting clinical trials)
- Can be used under the terms of this license for all cancer trials, including industry, investigator-initiated, etc.
- Cannot be used for non-cancer trials under the terms of this license

   ♦ If organizations want to extend the license to allow use in non-cancer trials, it would be a business discussion between the organization and the vendor, not involving NCI

CDMS Procurement License

- Unlimited-user, perpetual license, includes:

   ♦ On-site installation
   ♦ On-site administrator training
   ♦ User training materials
   ♦ Telephone / e-mail support
   ♦ Software upgrades

- Does not include:

    - Custom integration with existing / legacy systems
    - Migration of legacy data
- Onsite installation by vendor, or use NCI-hosted instance

    - Depending on demand, there may be a waiting list for onsite installation
    - Per license, vendor must be able to handle at least 55 installations over first four years

CDMS Deployment Process

The NCI will send out a request to the following three NCI caBIG® mailing lists:

- CABIG_ANNOUNCE@LIST.NIH.GOV
- CABIG_CTMS-L@LIST.NIH.GOV
- CABIG_CDMS@LIST.NIH.GOV

The request will ask organizations interested in deploying the CDMS within the next two years to provide nonbinding letters of intent (LOIs) indicating this interest. The request for LOIs will include information regarding the deployment options for the CDMS: locally-hosted installation, NCI-hosted installation, or third-party hosted installation, and ask organizations to select a likely preferred option. Organizations will have four weeks to return LOIs. Please note again that they are nonbinding and will only be used by NCI to determine the level of interest and the degree of prioritization required.

After the four week return period, the NCI will send out, to the same mailing lists, a request for deployment plans from organizations interested in deploying the CDMS within the next two years. NCI will supply a template for the deployment plan. The deployment plans will assist NCI in planning and coordinating the installations. Organizations will have three weeks to return the deployment plan. After the three week period for returning the deployment plans has passed, the NCI will prioritize the installations based on multiple criteria, including the organization?s readiness to begin using the CDMS and to do so successfully, as illustrated by the deployment plan.

Frequently Asked Questions

For additional information, visit our frequently asked questions page.

Contact Information

Questions regarding Contracts:

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Questions regarding CDMS Procurement:

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Questions regarding CDMS Deployment

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